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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,451	03/07/2002	Ernst Bernhard Grabitz	205,360	4546

7590 08/10/2005

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NEW YORK, NY 10017

EXAMINER
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SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/018,451

**Applicant(s)**

GRABITZ, ERNST BERNHARD

**Examiner**

Dr. Kailash C. Srivastava

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. The Art Unit Location to which your application has been assigned at the USPTO is changed to Art Unit 1655. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.
2. Applicant's responsive amendment filed 19 May 2005 in response to Office Action mailed 25 April 2005 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

## CLAIMS STATUS

3. Claims 34-49 are pending.

### *Restriction/Election*

4. Applicant, in response filed 19 May 2005 elects with traverse invention in Group I, Claims 1-48 in response to Restriction requirement in Office Action mailed 25 April 2005 is acknowledged and entered.

In accordance with applicant's traversal and provisions accorded to an application filed as a 371 of a PCT under MPEP §706.07(h), claims 34-48, directed to a process of making a product and Claim 49 drawn to a composition, namely a microorganism, previously withdrawn from consideration because of a restriction requirement, are now subject to being rejoined. Process claims 34-38 are hereby rejoined with the composition claim 49 and fully examined for patentability under 37 CFR §1.104.

5. Claims 34-49 are pending and are examined on merits.

## CLAIM OBJECTION

6. The following claims are objected to for the reasons given below:
  - Claim 36 is objected to because at Line one of the cited Claim, after the number "34" a --, -- should be inserted. Appropriate correction is required.
  - Claims 43-48 are objected to because at Line one of each one of the cited Claims, before the word "wherein" a --, -- should be inserted. Appropriate correction is required.

### **Claim Rejections Under 35 U.S.C. § 112**

7. Claims 34-49 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- To clearly communicate the claimed subject matter in Claims 34-49, Examiner suggests to re-write said claims clearly and succinctly, separately and distinctly describing each step and each ingredient/alternative step for Claims 34-41. Applicants are warned not to add any new matter while clearly and succinctly re-writing Claims 34-49. As an example Claim 34 can be clarified by rewriting as follows:

“A method to prepare an inactivated microorganism containing one or more e.g., water soluble compound having a pharmaceutical or nutraceutical activity upon administering to an individual in need thereof, wherein said method comprised the steps of:

- a. Drawing out the intracellular content of a given microorganism, while leaving intact the microbial membrane,
  - b. wherein the intracellular contents of said microorganism in step (a) above are drawn-out via treating said microorganism with a hypertonic solution,
  - c. recovering the “empty microorganism via separating the exudated intracellular contents of said microorganism from said empty microorganism,
  - d. wherein the empty microorganism obtained via the steps a-c above is inactivated by further treating said empty microorganism with a chemical or physical inactivation step,
  - e. loading the intracellular void of said inactivated empty microorganism obtained in steps a-d above with a water soluble substance having pharmaceutical or nutraceutical activity,
  - f. wherein said loading of said inactivated empty microorganism takes place under hypotonic or isotonic conditions via injecting a hypotonic or isotonic solution of a water-soluble substance having pharmaceutical or nutraceutical activity.”
- Phrase, “inactivated microorganism” in Claims 34-35 renders those claims vague, unclear and therefore, indefinite because metes and bounds for the phrase, “inactivated microorganism” are not defined. Does it mean that a microbial is not alive or is the microbial cell in a dormant state or the “inactive condition is temporary that will be returned to a n

active, metabolic state upon removal of physical or chemical stimulus that caused it to become inactive/ non-metabolizing or what? Appropriate clarification is required.

- The recitation "soluble" renders Claims 34 and 43 indefinite because this recitation in and by itself denotes a futuristic event. For e.g., if the substance can be dissolved in a certain solvent, what is the solvent and what are the conditions under which said substance will dissolve in a given solvent? The metes and bounds of the claimed subject matter are not clearly defined. Examiner suggests that the applicants define the metes and bounds of the term "soluble".
- The recitation "solubilizable" renders Claims 34 and 43 indefinite because this recitation in and by itself denotes a futuristic event. For e.g., if said substance is dissolved at some futuristic point, what are the conditions and materials for said dissolution, an acid, a base, an alkaline solution at normal pressure and temperature or there are other conditions/parameters under which said dissolution will take place? The metes and bounds of the claimed subject matter are not clearly defined. Examiner suggests that the applicants define the metes and bounds of the term "solubilizable".
- Recitation, "suitable microorganism" in claims 34 and 42 is unclear and indefinite. It is not clear how one can determine with clarity and accuracy when a given microorganism is suitable and what may be suitable for one, or under certain conditions, circumstances may not be suitable for another. Furthermore, what are the characteristics of a "suitable microorganism"? Applicant is advised to define the metes and bounds for the recitation, "suitable microorganism".
- The recitation, "optional" in claim 34 is indefinite because it is not clear how one can determine with clarity and accuracy when and by whom the "option" is to be exercised.
- The recitations, "characterized" renders claim 37 indefinite, because it is not clear whether the term includes other ingredients, like the conventional term "comprising", or whether the term excludes other ingredients like the conventional term "consisting of". The term will be read as including other ingredients. Examiner suggests that applicant use the term "having".
- The recitation, "optionally" in claims 38-39 is indefinite because the metes and bounds for said recitation are defined.
- Recitation "selected" in Claims 43 is similar to the word "preferably" and is indefinite because it is not clear how and who can determine with clarity and accuracy when the "selection" is to

be exercised and what are the metes and bounds of the term. Appropriate correction is required.

- The phrase "active principles of vegetable origin" in claim 46 renders that claim indefinite because the metes and bounds for the said phrase are not defined. Applicant should define the phrase "active principles of vegetable origin".

All other claims depend directly/indirectly from the rejected claims (e.g., Claim 34) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### **Claim Rejections - 35 U.S.C. §§ 102(b) and 103(a)**

8. Newly presented method Claims 34-48 and composition claim 49 that replace composition Claims 25-33 remain rejected under 35 U.S.C. § 102(b) as anticipated by Pannell (U.S. Patent 5,288,632) with evidence provided by Gruenwald et al (eds. PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pgs. 836-839) and Sagar et al. (WO 94/22572) for reasons set forth at pages 4-6, items 9-10 and 12 in the Office Action mailed 08/08/2003 and additional reasons discussed below.

9. Newly presented Claims 34-49 remain rejected as obvious under 35 U.S.C. § 103(a) over Pannell (U.S. Patent 5,288,632) with evidence provided by Gruenwald et al., in view of Sagar et al. (WO 94/22572) for reasons discussed *supra* and *infra*.

In response to the rejections cited *supra* in the Office Action mailed 09/23/2004, applicant in the response filed 11 February 2005 argue that the newly presented, amended Claims 34-49 submitted 11 February 2005 overcome said rejections and "should be withdrawn".

Applicant's above-cited arguments are fully and carefully considered but are not persuasive because Claims 34-49 still recite the same ingredients and steps as those recited in the cancelled claims 25-33. Furthermore, the net product is still a microorganism that is loaded with a pharmaceutical product under hypo/isotonic conditions and is therefore anticipated by and obvious over the cited references.

### **Conclusions**


10. For reasons aforementioned, no Claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Bruce Campbell, can be reached on (571)-272-0974 Monday through Friday 8:00 A.M. to 4:30 P.M. The

fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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August 4, 2005



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